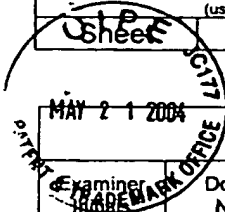


Substitute for form 1449A/PTO & 1449B/PTO		Complete if Known	
<b>FIRST INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)		Application Number	10/750,940
		Filing Date	January 5, 2004
		First Named Inventor	Thorsteinn LOFTSSON et al.
		Examiner Name	
		Attorney Docket Number	016914-039



U.S. PATENT DOCUMENTS				
Examiner Initials	Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Issue/Publication Date (MM-DD-YYYY)
	5,134,127	A	Stella et al.	07-28-1992
AAA	5,324,718		Loftsson	06-28-1994
AB	5,376,645		Stella et al.	12-27-1994
CAC	5,472,954		Loftsson	12-05-1995

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Examiner Initials	Document Number	Kind Code (if known)	Country	Date of Publication (MM-DD-YYYY)	Translation	
					Yes	No
AL	94/02518		WO	02-03-1994		

NON-PATENT LITERATURE DOCUMENTS	
Examiner Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
AR	Oh et al, <i>International Journal of Pharmaceutics</i> , 73, pp. 23-31 (1991).
AS	Loftsson and Brewster, <i>Pharm. Technol. Eur.</i> , 9(5), 26-34 (May 1997).
AT	Loftsson and Brewster, <i>J. Pharm. Sci.</i> , 85(10), 1017-1025 (October 1996).
AU	Rajewski and Stella, <i>J. Pharm. Sci.</i> , 85 (11), 1142-1169 (November 1996).
AV	Irie and Uekama, <i>J. Pharm. Sci.</i> , 86(2), 147-162 (February 1997).
AW	Stella and Rajewski, <i>Pharm. Res.</i> , 14(5), 556-567 (1997).
AX	Loftsson, <i>Pharmazie</i> , 53, 733-740 (1998).
AY	Frömming and Szejtli, <i>Cyclodextrins in Pharmacy</i> , Kluwer Academic Publishers, Dordrecht, The Netherlands, pp. 105-107 (1994).
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BS	Loftsson, Másson and Stefánsson, "Cyclodextrins as Permeation Enhancers", <i>Proceedings of the 17th Pharmaceutical Technology Conference and Exhibition</i> , volume 2, Dublin, pp. 313-324 (24-26 March 1998).
BT	Schwartz, Rhodes and Cooper, <i>J. Pharm. Sci.</i> , 66, 994-997 (July 1977).
	<del>Loftsson and Boder, <i>Acta Pharm. Nord.</i>, 1, 185-194 (1989). (Issue No. 4).</del>
BU	Loftsson and Sigurdardóttir, "Cyclodextrins as skin penetration enhancers," in J. Szejtli and Szenté (eds), <i>Proceedings of the Eighth International Symposium on Cyclodextrins</i> , Kluwer Academic Publishers, pp. 403-406 (1996).
Examiner Signature	L. E. Crane
Date Considered	01/13/2006

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

Substitute for form 1449A/PTO & 1449B/PTO		Con <input type="checkbox"/> if Known	
<b>FIRST INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Application Number	10750,940
		Filing Date	January 5, 2004
		First Named Inventor	Thorsteinn LOFTSSON et al.
		Examiner Name	
Sheet	2 of 2	Attorney Docket Number	016914-039

NON-PATENT LITERATURE DOCUMENTS	
Examiner Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
<i>PL</i> BV	Roth, Eger and Troschütz, <i>Pharmaceutical Chemistry</i> , Volume 2: Drug Analysis, Ellis Horwood, pp. 308-309 (1991).
<i>PL</i> BW	Gerecke, <i>Br. J. Clin. Pharmac.</i> , 11S-16S (1983).
<i>PL</i> BX	<i>Pharmaceutical Chemistry, Volume 2: Drug Analysis</i> , ed. H.J. Roth et al., pp. 302-311; 496-513; 518-525; 546-547; 580-581; 590-591; 594-597; 659-673; published by Ellis Horwood, London (1988).
<i>PL</i> BY	<i>Chemical Stability of Pharmaceuticals, A Handbook for Pharmacists</i> , Second Edition, ed. Kenneth A. Connors et al, pp. 257-263; 675-684; 764-773; published by Wiley-Interscience; John Wiley & Sons, New York (1986).
<i>PL</i> BZ	Stenlake, <i>Foundations of Molecular Pharmacology, Volume 1, Medicinal and Pharmaceutical Chemistry</i> , pp. 512-513, published by The Athlone Press, University of London (1979).
<i>PL</i> CR	Junquera et al, <i>J. Org. Chem.</i> , 63, pp. 4349-4358 (1998). (WWW publ.: 06/11/98).
<i>PL</i> CS	Li et al, <i>Journal of Pharmaceutical Sciences</i> , 87, No. 12, pp. 1535-1537 (December 1998).
<i>PL</i> CT	Krishnamoorthy et al., "Complexation of Weak Acids and Bases with Cyclodextrins: Effects of Substrate Ionization and the Estimation and Interpretation of Association Constants," <i>International J. of Pharmaceutical Advances</i> , 1 (3), 330-343 (Jan., 1996).
<i>PL</i> CU	Loftsson et al., "Effects of 2-Hydroxypropyl- $\beta$ -cyclodextrin on the Aqueous Solubility of Drugs and Transdermal Delivery of 17- $\beta$ -Estradiol," <i>Acta Pharm. Nord.</i> 1 (4), 185-194 (1989).
<i>PL</i> CV	Menard et al., "Studies on the Effect of pH, Temperature and ring Size on the Complexation of Phenytoin with Cyclodextrins," <i>Pharm. Acta Helv.</i> , 63 (11), 303-308 (1988).
<i>PL</i> CW	<del>Loftsson et al., "The Influence of Water Soluble Polymers and pH on Hydroxypropyl-<math>\beta</math>-cyclodextrin Complexation of Drugs," <i>Drug Development and Industrial Pharmacy</i>, 22 (5), 404-405 (1996); see also HCAPlus abstract.</del>
<i>PL</i> CX	Selva et al., "Study of the Salts of Organic Hydroxy Acids of the Terfenadine $\beta$ -Cyclodextrin Complex in Solution of Mass Spectrometry," <i>Journal of Mass Spectrometry</i> , 30 (1), 219-220 (1995).
<i>PL</i> CY	Fenyvesi et al., "Enhancement of the Drug Solubilizing Capacity of Hydroxypropyl- $\beta$ -cyclodextrin by Ternary Complex Formation," in <i>The 7<sup>th</sup> Cyclodextrin Symposium</i> , T. Osa (ed.), Business Center for Academic Societies Japan, Tokyo, Japan, 1994, pages 414-418.
<i>PL</i>	Vikmon et al., "Terfenadine/Cyclodextrin/Hydroxyacid Multicomponent Complexes," in <i>The 7<sup>th</sup> Cyclodextrin Symposium</i> , T. Osa (ed.), Business Center for Academic Societies Japan, Tokyo, Japan, 1994, pages 480-483.

Examiner Signature	L. E. Crane <i>LE Crane</i>	Date Considered	01/13/2006
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

Form PTO-892 U.S. Department of Commerce	Serial Number <b>10/750,940</b>	Group Art Unit <b>1623</b>	Attachment to Paper Number <b>01132006</b>	
Notice of References Cited	APPLICANT(S)			
	Loftsson et al.			

### U. S. Patent Documents

*		DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	Filing Date If Appropriate
*	A	5,134,127 A	07/28/92	Stella et al.	514	058.000	
	B	6,699,849 B1	03/02/04	Loftsson et al.	514	058.000	


### Foreign Patent Documents

*		DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUB-CLASS		
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### Other References (Including Author, Title, Date, Pertinent Pages, etc.)

*	R	Krishnamoorthy et al., "Complexation of Weak Acids and Bases with Cyclodextrins: Effects of Substrate Ionization and the Estimation and Interpretation of Association Constants," <i>International J. of Pharmaceutical Advances</i> , 1(3), 330-343 (Jan., 1996).
*	S <sup>†</sup>	Loftsson et al. (I), "Effects of 2-Hydroxypropyl-β-cyclodextrin on the Aqueous Solubility of Drugs and Transdermal Delivery of 17-β-Estradiol," <i>Acta Pharm. Nord.</i> , 1(4), 185-194 (1989).
*	T <sup>†</sup>	Menard et al., "Studies on the Effect of pH, Temperature and ring Size on the Complexation of Phenytoin with Cyclodextrins," <i>Pharm. Acta Helv.</i> , 63(11), 303-308 (1988).
*	U <sup>†</sup>	Loftsson et al. (II), "The Influence of Water-Soluble Polymers and pH on Hydroxylpropyl-β-cyclodextrin Complexation of Drugs," <i>Drug Development and Industrial Pharmacy</i> , 22(5), 401-405 (1996); see also HCAPlus abstract.

<sup>†</sup> Month of publication data is unavailable. Issue Number information is provided whenever possible following the volume number in parentheses.

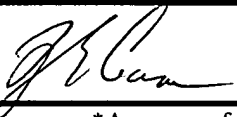
EXAMINER L. E. Crane 	DATE <b>01/13/06</b>	page 1 of 2 ¥: Reference not presently available.
*A copy of this reference is not being furnished with this office action. (See Manual of Patent Examining Procedure, Section 707.05(a).)		

Form PTO-892 U.S. Department of Commerce	Serial Number <b>10/750,940</b>	Group Art Unit <b>1623</b>	Attachment to Paper Number <b>01132006</b>	
Notice of References Cited	APPLICANT(S)			
	Loftsson et al.			

**Other References (Including Author, Title, Date, Pertinent Pages, etc.)**

*	V†	Selva et al., "Study of the Salts of Organic Hydroxy Acids of the Terfenadine $\beta$ -Cyclodextrin Complex in Solution by Mass Spectrometry," <i>Journal of Mass Spectrometry</i> , 30(1), 219-220 (1995).
*	W†	Fenyvesi et al., "Enhancement of the Drug Solubilizing Capacity of Hydroxypropyl- $\beta$ -cyclodextrin by Ternary Complex Formation," in <u>The 7th Cyclodextrin Symposium</u> , T. Osa (ed.), Business Center for Academic Societies Japan, Tokyo, Japan, 1994, pages 414-418.
*	X†	Vikmon et al., "Terfenadine/Cyclodextrin/Hydroxyacid Multicomponent Complexes," in <u>The 7th Cyclodextrin Symposium</u> , T. Osa (ed.), Business Center for Academic Societies Japan, Tokyo, Japan, 1994, pages 480-483.

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EXAMINER L. E. Crane 	DATE <b>01/13/06</b>	<b>page 2 of 2</b> ¥: Reference not presently available.
*A copy of this reference is not being furnished with this office action. (See Manual of Patent Examining Procedure, Section 707.05(a).)		